Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BURKHARD SCHLUTERMANN

Appeal No. 2004-0377
Application No. 09/367,361

ON BRIEF

Before ADAMS, MILLS and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 16-20, which are all the claims pending in the application.

Claim 16 is illustrative of the subject matter on appeal and is reproduced below:

16. A film-coated tablet comprising:
    a) a tablet core comprising a therapeutically effective dose of oxacarbazepine and excipients that are suitable for the production of granules, wherein said oxacarbazepine has a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5%; and
    b) a single hydrophilic permeable coating.

The examiner relies on the following reference:

Bourquin 5,472,714 Dec. 5, 1995

GROUND OF REJECTION

Claims 16-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bourquin.

We reverse.

DISCUSSION

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of going forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). On this record, the examiner finds (Answer, bridging paragraph, pages 2-3), Bourquin

> teaches color-stable tablets comprising: (1.) [a] therapeutic drug oxcarbazepine[1] tablet core prepared by a compacting method. Dry granulation is followed by compressing the active agent with the adjuncts to form larger objects such as coarse lumps, followed by comminuting these by grinding and compressing the grinding stock to tablet cores. See column 2, lines 14-27, column 2, line 52 to column 3, line 15. [sic] and (2. a hydrophilic, permeable outer layer containing white pigments in combination with iron (II) oxide pigments. See Abstract.

According to the examiner (Answer, page 4), "[t]he difference between the claimed invention and the teachings of the Bourquin reference is that appellant includes the particle size distribution for the oxcarbazepine which is described in the specification as preferred, not as critical nor established as critical to the

[1] According to appellant (Brief, page 2), "'oxcarbazepine' and 'oxacarbazepine' are equivalents...."

composition...." To make up for this deficiency in Bourquin, the examiner relies on several conclusory statements as to what is "generally accepted" or "well known" in the art. Specifically, the examiner asserts:

1. It is generally accepted in the art that drugs in the form of particles are easily dispersed or dissolved in the system for its quick action. Id.

2. [I]t is generally accepted in the art that drugs should be in finely ground state to be immediately available to the system at the point of desired delivery. Answer, page 5

3. It is well known in the art that drugs in the form of finite particles are easily dispersed, dissolved and absorbed into the system. Id.

From these conclusions, the examiner asserts (id.), since "[a]ppellant uses the same conventional grinding process as the reference[,] [t]he particle size distribution in the reference tablet is expected to be essentially identical with or similar to the appellant's claimed size distribution." Accordingly, the examiner finds (id.),

> [i]t would have been obvious to one of ordinary skill in the art to follow the teachings of Bourquin and formulate the same tablet with a core of oxcarbazepine and other excipients using conventional coating techniques for an outer layer comprising white pigments and iron oxide pigments including a non-critical particle size distribution for the core drug within the range of applicant's.

In response, appellant asserts, inter alia, "[a]ppellant defines particle size and particle size distribution for oxacarbazepine in the application on page 6, lines 9-13, as a median particle size of approximately 2 μm to 12 μm, and a maximum residue on a 40 μm sieve of less than or equal to 5%." Brief, page 3. We note that appellant's claims include limitations consistent with appellant's disclosure. See e.g., claim 16, from which claims 17-20 ultimately depend. In this regard, appellant argues (id.), "[t]he only mention Bourquin, makes of particle size is in Example 1 where Bourquin prepares

oxacarbazepine tablets by compacting a mixture of oxacarbazepine and excipients to 2-6 mm coarse granules." Accordingly, appellant concludes (id.), "the selection of oxacarbazepine having a median particle size of approximately 2 µm to 12 µm, and a maximum residue on a 40 µm sieve of less than or equal to 5% ... is simply not taught or suggested by Bourquin."

Initially, we note that appellant does not dispute the examiner's assertion (Answer, page 5), "[a]ppellant uses the same conventional grinding process as the reference." Nevertheless, we recognize appellant's argument that Bourquin does not teach oxcarbazepine having the same particle size as set forth in appellant's claimed invention. According to Bourquin, oxcarbazepine (TRILEPTAL) is mixed with other excipients, and then "compacted to c. 2-6 mm coarse granules.... The compacted product is then ground to granulates having an average particle size of c. 400 µm." Bourquin, column 6, lines 1-9. Thus, even if the same grinding process was utilized, there is no evidence on this record that Bourquin ground the oxcarbazepine mixture to a particle size consistent with appellant's claimed invention. Accordingly, we disagree with the examiner's conclusion (Answer, page 5) that the "particle size distribution in the reference tablet is expected to be essentially identical with or similar to the appellant's claimed size distribution."

We recognize that it is proper to evaluate a reference not only for its express teachings, but also for what a person of ordinary skill in the art would reasonably infer from the reference. In re Shepard, 319 F.2d 194, 197, 138 USPQ 148, 150 (CCPA 1963). However, based on the evidence before us, we do not find that a person of

ordinary skill in the art would have reasonably inferred from Bourquin that the oxcarbazepine mixture should be further ground to the specific particle size set forth in appellant's claimed invention. The conclusory statements of what the examiner believes to be "well known" or "generally accepted" in the art do not lead a person of ordinary skill in the art to appellant's claimed particle size. In this regard, we remind the examiner that "conclusory statements" as to teaching, suggestion or motivation to arrive at the claimed invention "do not adequately address the issue [of obviousness]." In re Lee, 277 F.3d 1338, 1343-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

For the foregoing reasons, it is our opinion that the examiner failed to meet his burden of providing the evidence necessary to establish a prima facie case of obviousness. Accordingly, the rejection is reversed.

Having determined that the examiner has not established a prima facie case of obviousness, we find it unnecessary to address appellant's arguments regarding unexpected results.

REVERSED

Donald E. Adams)
Administrative Patent Judge)
)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Eric Grimes) INTERFERENCES
Administrative Patent Judge)

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